U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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PROTECTING THE FOOD SUPPLY:
FDA Actions on New Bioterrorism Legislation

On June 12 President George W. Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) which includes a large number of provisions to help ensure the safety of the U.S. from bioterrorism, including new authority for the Secretary of Health and Human Services (HHS) to take action to protect the nation's food supply against the threat of intentional contamination. The Food and Drug Administration (FDA), as the food regulatory arm of HHS, is responsible for developing and implementing these food safety measures, including four major regulations. This brochure is intended to provide an overview of the food safety provisions of the law. Additional information about provisions of the Bioterrorism Act under FDA's jurisdiction and the agency's implementation plans is available at http://www.fda.gov/oc/bioterrorism/bioact.html.

New Regulations

FDA will propose regulations on the following major provisions of the Bioterrorism Act. Except for the specified exemptions, these new regulations will apply to all facilities for all foods and animal feed products regulated by FDA, including dietary supplements, infant formula, beverages (including alcoholic beverages), and food additives.

- ***Registration of Food Facilities***—Domestic or foreign facilities that manufacture, process, pack, distribute, receive, or hold food for consumption by humans or animals in the U.S. must register with the FDA no later than **December 12, 2003**. Registration will consist of providing information, including firm name, address, etc., to FDA. Farms, restaurants, retail food establishments, non-profit establishments that prepare or serve food, and fishing vessels not engaged in processing as defined in *21 CFR 123.3 (k),* and facilities that are regulated exclusively by the U.S. Department of Agriculture are exempt from this requirement. Also exempt are foreign facilities if the food from the facility undergoes further processing or packaging by another facility outside of the U.S. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities would be required to register. FDA must have final regulations in effect no later than December 12, 2003, but facilities must register by this date in accordance with the Bioterrorism Act even if the regulations are not in effect . There is no fee associated with registration.
- ***Prior Notice of Imported Food***—*Beginning* on December 12, 2003, FDA must receive advance notice of each shipment of food into the U.S. The notice must include a description of all articles, each article's manufacturer and shipper, grower (if known), originating country, country from which the article is shipped, and anticipated port of entry. FDA must have final regulations in effect by December 12, 2003. If the regulations are not in effect by that date, the Act still requires importers to provide notice to FDA no less than 8 hours and no more than 5 days prior to shipment until the regulations take effect.
- ***Establishment and Maintenance of Records***— Persons that manufacture, process, pack, transport, distribute, receive, hold, or import food will be required to create and maintain records that FDA determines are necessary to identify the immediate previous sources and the immediate subsequent recipients of food (i.e., where it came from and who received it). This would allow FDA to follow up on credible threats of serious adverse health consequences or death to humans or animals by tracing the food back to its source. Farms and restaurants are exempt from this requirement. FDA must issue final regulations by December 12, 2003.

- ***Administrative Detention***—Authorizes FDA to administratively detain food if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. The Act requires FDA to issue regulations to provide procedures for instituting on an expedited basis certain enforcement actions against perishable foods, but does not specify a deadline.

New Guidance

The Bioterrorism Act includes several provisions for which FDA is currently considering guidance. Some of the provisions are:

Debarment—Authorizes FDA to debar (prohibit from importing food) persons who have been convicted of a felony relating to the importation of any food or who have engaged in a pattern of importing adulterated food that presents a threat of serious adverse health consequences or death to humans or animals. Food imported by a debarred person or with the assistance of a debarred person will be held at the port of entry into the U.S. Food so held may be delivered to non-debarred persons who demonstrate—at their expense—that the food is in compliance with FDA standards.
Marking—The Secretary may require marking (labeling) of foods refused admission into the U.S. Marking shall be at the owner's or consignee's expense.
Port Shopping—Food that has been refused admission into the U.S. is adulterated if it is offered again for import, unless the person importing the food or offering it for import demonstrates that the food is now in compliance with FDA standards.
Import for Export—FDA has already announced the availability of guidance regarding the importation of certain articles (including food additives, color additives, or dietary supplements) that are not otherwise permitted in the U.S to be offered as "imports for export." The guidance describes the legal requirements for such imports, including that the articles must be further processed or incorporated into products that will be exported from the U.S. by their initial owner or consignee, that the importer must provide certain information at the time of initial importation, that a bond is posted, and that the initial owner or consignee must maintain certain records. However, the Secretary may refuse admission if there is credible evidence that such article is not intended to be further processed or incorporated into a product that will be exported.

Single copies of this document, *Regulatory Procedures Manual, Chapter 9, Subchapter Import for Export*, are available from the Division of Import Operations and Policy (HFC-170), Office of Regulatory Affairs, 5600 Fishers Lane, Rockville MD 20852. A copy can be obtained electronically at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9impex.html.

Opportunities for Public Comment

***Comments on Proposed Regulations*:** Under U.S. law, proposed regulations are published in the *Federal Register* to provide interested parties with an opportunity to submit comments, e.g., suggestions to make the proposal more effective or less burdensome, questions regarding the agency's data or assumptions, submission of information the agency may not have, etc. Comments on the proposed regulations outlined above will be accepted for 60 days from their date of publication. FDA will consider all timely comments that it receives as it develops the final registration rule, which will be published in the *Federal Register*. Regularly updated information on these regulatory proposals and how to comment on them can be accessed electronically at http://www.fda.gov/oc/bioterrorism/bioact.html. To obtain single copies of these proposed regulations once they have been published, write Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

***Comments on Guidance*:** FDA will accept comments on draft guidance documents before issuing a final guidance. FDA also accepts comments on final guidance documents after they are issued. FDA is currently receiving comments on the guidance document *Regulatory Procedures Manual, Chapter 9, Subchapter Import for Export (*Docket Number 02D-0402).

Written comments on proposed regulations and/or guidance documents can be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can be sent electronically to www.fda.gov/dockets/ecomments. It is important to include the docket numbers when providing comments.